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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/031,187

06/12/2002

Michael Hallek

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06/23/2006

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

HURT, SHARON L

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/031,187		HALLEK ET AL.	
	Examiner		Art Unit	
	Sharon Hurt		1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-29,33,34,36-43,45,47,49,51,53,55,57,59 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29,33,34,36-43,45,47,49,51,53,55,57,59 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>Feb. 6, 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's submission of amendments to the claims and specification in the reply filed on March 20, 2006 is acknowledged. Claims 30-32, 35, 46, 48, 50, 52, 54, 56, 58 and 60-64 have been canceled. Claims 27-29, 33-34, 36-43, 45, 47, 49, 51, 53, 57, 59 and 65 are examined on the merits.

Response to Arguments

Claim Rejections - 35 USC § 112

The rejection of claims 27-28, 35-36 and 60-64 under 35 U.S.C. 112, second paragraph is withdrawn pursuant to applicant's amendments. Claims 35 and 60-64 have been canceled.

The rejection of claims 31 and 46 under 35 U.S.C. 112, first paragraph is moot, as the claims have been cancelled.

The rejection of claims 36 and 47 under 35 U.S.C. 112, first paragraph lacking an enabling disclosure is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues (page 11 of the response) that applicants have identified particular AAV sites amenable to amino acid insertions and have provided exemplary methods for making insertions and testing for infectivity (pages 16-26 of the specification). Applicant's arguments, however, are not commensurate in scope with

the invention, as claimed. The claims encompass any and all mutations in the VP3 either before or after any one of the amino acids recited in any of SEQ ID NO's 2-7. Therefore, given the broadest reasonable interpretation of the claims, the claims encompass any mutation (insertion, deletion, or substitution) anywhere in the VP3 protein before or after any amino acid, as long as it is one of the amino acids which appears in one of the recited sequences. Applicant's disclosure and examples are limited to specific insertions at particular locations. There is no guidance provided as to what other types of mutations can be made.

Claim Rejections - 35 USC § 102

The rejection of claims 27-29, 30, 34, 36, 38-43, 45 and 47 under 35 U.S.C. 102(e) as being anticipated by US Patent Number 6,491,907 is maintained. Claims 30, 32, 35, 46, and 60-64 have been canceled.

Applicant's arguments regarding the rejection of these claims have been considered but are not found persuasive. Applicant argues that claim 27 has been amended to include the limitations of the original claim 58 therefore the rejection should be withdrawn. Applicant argues that claim 37 now includes the limitation through claim 27 (from original claim 58) therefore the rejection as obvious over Patent No's: 6,491,907 and 5,276,136 may be withdrawn.

This is not persuasive because newly amended claim 27 reads on at least one mutation, before and/or after, at least one amino acid in the sequence. The mutation doesn't have to be anywhere in the recited sequences themselves, but rather can be in

any amino acid anywhere C or N terminally to any of the amino acids in any of the recited sequences. Therefore the art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The rejection of claim 37 under 35 U.S.C. 103(b) as being unpatentable over US Patent Number 5,276,136 is maintained.

The rejection of claims 46-59 under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,491,907 in view of Spear et al. or Yang et al. is maintained. Claims 46, 48, 50, 52, 54, 56 and 58 are canceled. Claims 47, 49, 51, 53, 55, 57 and 59 stand rejected.

Applicant's arguments regarding the rejection of these claims have been considered but not found persuasive. Applicant argues that claim 27 has been amended and now includes the limitation of original claim 58, a claim not rejected in office action, therefore should be withdrawn.

This is not persuasive because of the reasons set forth above.

The rejection of claims 58-59 under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,491,907 in view of Ruffing is maintained. Applicant argues that the Patent reference does not disclose the specific mutations recited in claim 27 and Ruffing does not cure this deficiency. Applicant argues that Ruffing does not provide an AAV structural protein as recited in the newly amended claim 27.

This is not persuasive because of the reasons set forth above.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 and dependant claims 28-29, 33-34, 36-43, 45, 47, 49, 51, 53, 55, 57, 59 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 recites "said method comprising providing AAV particles having a structural protein of adeno-associated virus that comprises at least one mutation in the VP3 located before and/or after at least one amino acid in the sequence". The claim interpretation is broad and reads on any mutation, including a mutation before or after said sequences. The claim language does not clearly define the metes and bounds of the claim invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 and dependant claims 28-29, 33-34, 36-43, 45, 47, 49, 51, 53, 55, 57, 59 and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case the claim language in claim 27, described above, is not described in the specification.

This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly &*

Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

There are a limited number of species of the claimed genus disclosed that are within the scope of the claimed genus, *i.e.* amino acid sequences SEQ ID NO:2, 3, 4, 5, 6 and 7, 8 and 9. The disclosure of even a single species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described, namely species drawn to mutations (including insertions, deletions, and substitutions) anywhere before and/or after any amino acid in the specified sequences. Thus, there is substantial variability among the species. In the absence of sufficient recitation of distinguishing characteristics of the genus, the specification does not provide adequate written description of the claimed genus. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the

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genus. The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wilson and Xiao (WO-US025694, Nov. 1999) describe a sequence with 100% homology to applicant's SEQ ID NO:3 (see Sequence 534).

Anderson et al. (WO-200021983, Oct. 1999) describe a sequence with 100% homology to applicant's SEQ ID NO:6 (see Sequence 105).

Pelletier et al. (WO-200032825, Dec. 1999) describe a sequence with 100% homology to applicant's SEQ ID NO:7 (see Sequence 34).

Kleinschmidt et al. (DE-19849643, Oct. 1998) describe a sequence with 100% homology to applicant's SEQ ID NO:8 (see Sequence 22).

Conclusion

This office action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334.


The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

14 June 2006


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